

Notice of Allowability

Application No.

10/089,394

Examiner

Maria B. Marvich, PhD

Applicant(s)

CHEN ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to an amendment 3/17/06.
2. ☒ The allowed claim(s) is/are 4-18,24 and 29-31.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

ALLOWANCE

This office action is in response to an amendment filed 3/17/06. Claims 1-3, 19-23 and 25-28 have been cancelled. Claims 12, 24 and 31 have been amended.

Claims 4-18, 24 and 29-31 are under examination in this application.

Drawings

Acknowledgement is made of receipt of replacement drawings for Figures 6 and 7. However, the replacements have not corrected the condition of the drawings. Therefore, figures 6 and 7 are objected to under 37 CFR 1.83(a) because they fail to show any details as described in the specification. Specifically, both figures are graphs. However, the black bars are presented on a black background. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. It would be remedial to put the black bars on a white background.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gladys Monroy on June 8, 2006

The claims have been amended as follows:

IN THE CLAIMS:

Claim 12 (amended): A method for producing rAAV, comprising the steps of:

- a) infecting a host cell comprising a rAAV genome with the adenovirus according to claim 5, 6 or 7 wherein the infected host cell comprises helper functions and Cap coding sequences;
- b) growing the host cells under conditions in which rAAV is produced; and
- c) optionally collecting the rAAV from the host cells.

Claim 30 (amended): A method for producing rAAV, comprising the steps of, growing a host cell comprising a rAAV genome and an adenovirus according to claim 5, 6 or 7 under conditions in which rAAV is produced and wherein the host cell further

Art Unit: 1633

comprises helper functions and Cap coding sequences; and optionally collecting the rAAV from the host cells.

In claim 31, line 3, the word “it” prior to the phrase “has been introduced” has been deleted and replaced with the phrase -- the adenovirus vector --.

Insert after page 65 and before the claims

ABSTRACT

This invention relates to novel adenoviruses useful in the production of high titers of recombinant adeno-associated virus (rAAV) comprising a foreign DNA insert and methods of making these adenoviruses. The adenovirus comprises the AAV rep gene in which the p5 promoter is replaced by a minimal promoter or by no promoter. The invention also provides methods of producing high levels of rAAV as a substantially homogenous preparation and composition of rAAV.

Conclusion

Claims 4-18, 24 and 29-31 re allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1633

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1633

June 7, 2006



DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER